

## Conclusions for Chapter 8.

Jim, I have exploded the version you sent Dave and I on March 10, and suggested changes and provided comment on my suggested changes.

I have then put it all back together in a revised version down below.

Please let me know what you think of my changes and rationale for my suggested changes.

Text Provided in Email dated 3/10/14	Suggested Change	Comments
Harmonizing tier testing among regulators in different countries would facilitate greater precision in risk assessment for candidate agrochemicals.	Ok, looks good.	1.
Although laboratory toxicity and sub-lethal tests are currently available for evaluating potential effects of chemicals on adults and larval bees, no agreement exists among different countries on which <del>ones</del> tests to include for further development.	Ok, looks good.	2.
Suggestions are given in Chapters 5 and 6 and appendix 6 for inclusion of a new tier 1 system for systemically active materials separate from that for sprayed materials.	Overall efforts of the Workshop reflect the belief that an adequate risk assessment process for bees, and the data needed to inform that process must account for systemically active pesticides, in addition to foliar applied pesticides.	3.
The parallel tier 1 testing of active ingredients and formulation blanks was also seen as an important improvement in need of harmonization.	??	4. Jim, I do not recall much discussion about the process and merits of testing formulation blanks, and the chapter does not discuss it much either. Is this an element that can be captured in another fashion, either: (i) modify the sentence to say it is an idea that was raised but needs more investigation; or (ii) put it into the Recommendations Section.
The participants dealing with laboratory testing improvements agreed that the adult bee 10 day feeding test and the larval <i>in vitro</i> contact/feeding test are both high priority changes to be adopted in the shortest possible time, and the details provided in appendices 1 and 6 are	The participants dealing with laboratory testing improvements agreed that priority should be given to developing the adult chronic laboratory test (see Appendix 1), and the larval <i>in vitro</i> test for application as a standard tier 1 study within regulatory frameworks.	5. Jim, I have softened the language of this sentence. Both Dave and I believe that this effort is not intended to give such direct policy or science policy recommendations. For sure, the nature of the effort is intended to be a source of information that ought to be

given to facilitate these changes.		<p>considered by the regulating and regulated community (and others) as balanced, objective scientific opinion; but, the way in which it is being delivered has been a focus that we have applied consistently throughout the proceedings.</p> <p>Also, I have included reference to the relevant part of the Appendices, i.e., Appx. 1 which is which is the chronic bench study material.</p>
Participants also agreed that the sub-lethal tests enumerated here are likely candidates for improving the tiered testing system, and further hypothesis testing to link these observed effects on individual adult and larval bees to measurable end points affecting colony population dynamics and reproduction should be given a high research priority.	Participants also agreed that the regulatory testing framework incorporate sublethal endpoints (e.g., changes in behavior or body condition) at the individual and/or the colony level; and that further research to link observed [sublethal] effects on individual (adult and larval) to apical end points at the colony level should be given a high research priority.	<p>6. Jim, I modified the first part of the sentence because I think it is stronger (and more inclusive) to indicate the need for measuring sublethal endpoints in all tests (Tier I thru Tier III) versus inclusion of specific sublethal tests.</p> <p>I also modified the second half of the sentence to be a bit closer to the Research Recommendation that is captured in Chap. 14, and to use terms (i.e., “apical end point”) that is used/referred to in other parts of the book.</p>
Participants also agreed that the honey bee is not an adequate surrogate species for most non- <i>Apis</i> bees and that multiple species are available to use as indicators of the sensitivity of the agro- ecosystems of different countries.	Participants also agreed that the honey bee may not be an adequate surrogate species for many non- <i>Apis</i> bees and that other species are available for inclusion in testing, which may provide broader reflection of potential bee/pollinator sensitivity to pesticides.	<p>7. Jim, I’ve modified this sentence to (i) soften the language... I think to flat-out say that <i>Apis</i>-m is not an adequate surrogate species is to state it further and stronger than everywhere else in the book where we have touched upon this ... I think all of us would agree that this is a reasonable conclusion, but where this effort was in 2011 was to clearly this point ... but not to put such a fine point on it. I modified the second half of the sentence to make it a bit clearer to me.... I hope I maintained your message/intent.</p>
Adding two or more non- <i>Apis</i> bees is a realistic goal among the EU, US, and Canada in the near term, and participants recommended these be made priority changes.	Consequently, participants agreed that efforts should be made to expand the range of test species to include two or more non- <i>Apis</i> bees in a pesticide risk assessment for pollinators.	<p>8. Jim, Here I am suggesting a slight softening of the language (recommendation), and editorial modifications.</p>

### **Based on the Above, a Proposed Final Conclusion Would Be:**

Participants of the laboratory testing workgroup believe that harmonizing tier testing among regulatory authorities in different countries would facilitate greater precision in risk assessment for candidate agrochemicals. Although laboratory acute, and sub-lethal toxicity tests are currently available for evaluating potential effects of chemicals on adults and larval bees, no agreement exists among different countries on which tests to include for further development. The overall efforts of the Workshop reflect the belief that an adequate risk assessment process, as well as the data needed to inform such a process for bees, must account for systemically active pesticides, in addition to foliar applied pesticides and that: parallel testing of active ingredients and formulation blanks in Tier 1 studies as is currently done in the EU would offer further improvement. The participants dealing with laboratory testing improvements agreed that priority should be given to developing the adult chronic laboratory test (see Appendix 1), and the larval *in vitro* test for application as a standard Tier 1 study within regulatory frameworks. Participants also agreed that the regulatory testing framework should incorporate sub-lethal endpoints (e.g., changes in behavior or body condition) at the individual and/or the colony level; and that further research to link observed (sub-lethal) effects at the individual-level (adult and larval) to apical end points at the colony level should be given a high research priority (see Chapter 14). Participants also agreed that the honey bee may not be an adequate surrogate for many non-*Apis* bees and that there exists other species, available for inclusion in testing, which may provide a reflection of the broader potential bee/pollinator sensitivity to pesticides. Consequently, participants agreed that efforts should be made to expand the range of test species to include two or more non-*Apis* bees in a pesticide risk assessment framework for pollinators.

#### Comments on suggested final Conclusions

I have numbered Tom's comments section in the above table and list my responses below:

1-4. Agree

5. There was some confusion among our group as to whether this was a current requirement in the EU, but if so, we agreed it should be incorporated in harmonizing efforts. I have since seen reference to this parallel testing as an EU requirement, so would want to keep this in as a priority goal for consideration in harmonizing efforts. If adopted, this would greatly improve the US risk assessment as I see it. As I read the recommendations section it covers only suggestions for

further research, but I think this is more of a recommendation for harmonizing with the EU in US, Canada, and for others to consider; thus I would suggest a modified sentence in the conclusions and have suggested such.

6. Agree

7. Obvious to me and probably most researchers even if not agreed to by risk assessors. A toss up for this chapter conclusion, since researchers were doing the discussing and risk assessors were not part of the discussion. Helen was probably the sole person with enough experience in both arenas to gauge this. Our current paper on Osmia vs. Honeybee shows a 1000x range of differences among common orchard pesticides between these two species, so the probability of other materials and other species showing similar differences makes this obvious that the HB give such limited info, it is not worth continuing as a “substitute”.

8 Agree.